



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval;
Public Comment Request**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: Information Collection Request Title: Data System for Organ Procurement and Transplantation Network OMB No. 0915-0157– Revision

Abstract: Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to current OPTN data collection forms associated with donor organ procurement and an individual’s clinical characteristics at the time of registration, transplant, and follow-up after the transplant.

Need and Proposed Use of the Information: Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used to develop transplant, donation and allocation policies, to determine whether institutional members are complying with policy, to determine member-specific performance, to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the

Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

Likely Respondents: Transplant programs, organ procurement organizations, histocompatibility laboratories, medical and scientific organizations, and public organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	58	158.2	9174	1.1	10091.4
Living Donor Registration	296	20.2	5984	1.8	10771.2
Living Donor Follow-up	296	59.5	17610	1.3	22893.0
Donor Histocompatibility	154	94.8	14598	0.2	2919.6
Recipient	154	170.1	26199	0.4	10479.6

Histocompatibility					
Heart Candidate Registration	131	30.5	3991	0.9	3591.9
Heart Recipient Registration	131	19.3	2525	1.4	3535.0
Heart Follow Up (6 Month)	131	17.0	2229	0.4	891.6
Heart Follow Up (1-5 Year)	131	73.9	9683	0.9	8714.7
Heart Follow Up (Post 5 Year)	131	115.2	15091	0.5	7545.5
Heart Post-Transplant Malignancy Form	131	11.0	1447	0.9	1302.3
Lung Candidate Registration	65	39.0	2534	0.9	2280.6
Lung Recipient Registration	65	29.6	1923	1.4	2692.2
Lung Follow Up (6 Month)	65	25.8	1677	0.5	838.5
Lung Follow Up (1-5 Year)	65	97.9	6364	1.1	7000.4
Lung Follow Up (Post 5 Year)	65	64.6	4201	0.6	2520.6
Lung Post-Transplant Malignancy Form	65	1.5	99	0.4	39.6
Heart/Lung Candidate Registration	63	0.7	46	1.1	50.6
Heart/Lung Recipient Registration	63	0.3	21	1.4	29.4
Heart/Lung Follow Up (6 Month)	63	0.3	20	0.8	16.0
Heart/Lung Follow Up (1-5 Year)	63	1.5	97	1.1	106.7
Heart/Lung Follow Up (Post 5 Year)	63	3.1	194	0.6	116.4
Heart/Lung Post-Transplant Malignancy Form	63	0.2	12	0.4	4.8
Liver Candidate Registration	136	88.6	12048	0.8	9638.4
Liver Recipient	136	47.5	6457	1.3	8394.1

Registration					
Liver Follow-up (6 Month – 5 Year)	136	229.4	31194	1.0	31194.0
Liver Follow-up (Post 5 Year)	136	254.6	34622	0.5	17311.0
Liver Recipient Explant Pathology Form	136	12.2	1665	0.6	999.0
Liver Post- Transplant Malignancy	136	13.1	1786	0.8	1428.8
Intestine Candidate Registration	41	4.4	182	1.3	236.6
Intestine Recipient Registration	41	2.7	109	1.8	196.2
Intestine Follow Up (6 Month – 5 Year)	41	13.3	547	1.5	820.5
Intestine Follow Up (Post 5 Year)	41	13.5	553	0.4	221.2
Intestine Post- Transplant Malignancy Form	41	0.6	25	1.0	25.0
Kidney Candidate Registration	235	161.2	37880	0.8	30304.0
Kidney Recipient Registration	235	71.9	16904	1.3	21975.2
Kidney Follow-Up (6 Month – 5 Year)	235	376.3	88422	0.9	79579.8
Kidney Follow-up (Post 5 Year)	235	343.7	80770	0.5	40385.0
Kidney Post- Transplant Malignancy Form	235	17.9	4213	0.8	3370.4
Pancreas Candidate Registration	135	3.5	479	0.9	431.1
Pancreas Recipient Registration	135	1.9	259	1.1	284.9
Pancreas Follow- up (6 Month – 5 Year)	135	10.4	1398	1.0	1398.0
Pancreas Follow- up (Post 5 Year)	135	13.4	1804	0.5	902.0

Pancreas Post-Transplant Malignancy Form	135	0.8	108	0.6	64.8
Kidney/Pancreas Candidate Registration	13	98.5	1280	0.9	1152
Kidney/Pancreas Recipient Registration	135	5.6	760	1.1	836.0
Kidney/Pancreas Follow-up (6 Month – 5 Year)	135	33.4	4509	1.0	4509.0
Kidney/Pancreas Follow-up (Post 5 Year)	135	47.9	6465	0.6	3879.0
Kidney/Pancreas Post-Transplant Malignancy Form	135	1.6	211	0.4	84.4
Vascular Composite Allograft Candidate Registration	16	0.9	15	0.4	6.0
Vascular Composite Allograft Recipient Registration	16	0.9	15	1.3	19.5
Vascular Composite Allograft Recipient Follow Up	16	0.9	15	1.0	15.0
Total	456*		460414		358092.5

*Total number of OPTN member institutions as of 09/9/2014. Number of respondents for transplant candidate or recipient forms based on number of organ specific programs associated with each form.

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